

## R E M A R K S

The office action of August 6, 2008 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is requested. Claims 10 through 18 remain in this case, claims 10 through 13 being amended by this response. No new matter has been added. More specifically, the amendments are fully supported by the application as filed, for example on page 5, lines 17-21, page 6, lines 20-26, page 7, lines 20-23, page 8, lines 9-17, page 10, lines 1-13, page 16, lines 15 through page 18, line 10.

The numbered paragraphs below correspond to the numbered paragraphs in the Office Action.

### **Rejections under 35 U.S.C. §112**

4. Claims 10-13 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10-13 have been amended to overcome this rejection. More specifically, “and/or” has been removed from the claims. In addition, claims 11 and 13 have been amended to remove the “control signal to be sent outside” language.

Applicant believes that these amendments have fully addressed the Examiner's rejections, and the claims are now in condition for allowance. Reconsideration and withdrawal of the rejection are respectfully requested.

### **Rejection(s) under 35 U.S.C. §103**

8. Claims 10-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor et al. (3,943,936) in view of Heller (6,294,281). Applicant respectfully disagrees with this rejection.

As amended, claims 10-13 include, in part, “wherein the control unit includes a stimulation timing determining means that decides the timing of stimulation to generate control signals, and a stimulation timing changing means that changes the timing of stimulation to

generate control signals; wherein the control unit changes the stimulation timing when certain conditions are fulfilled.”

Neither Rasor et al. nor Heller teach or suggest a change in stimulation timing triggered by the fulfillment of certain conditions.

Claims 10-13 also include, in part, “wherein the biological fuel cell comprises an anode electrode coated with an immobile layer formed by immobilization of mediators and oxidative enzymes for biological fuels, wherein said immobile layer prevents oxygen existing in a biological body from contacting said anode electrode and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions”. These features efficiently promote reaction at the anode and cathode.

Neither Rasor et al. or Heller teach or suggest an immobile layer on the anode electrode that prevents oxygen existing in a biological body from contacting the anode electrode. In addition, neither Rasor et al. nor Heller teach or suggest a coating on a surface of a cathode electrode that prevents permeation of the reactive substances and allows permeation of oxygen and hydrogen ions.

Claims 10-13 also include, in part, “wherein said anode electrode and said cathode electrode contact the electrolyte solution”.

As the Examiner acknowledges, Rasor et al. does not teach a biological fuel cell. Heller teaches a biological fuel cell that includes various artificial compounds as mediators containing elements including osmium, ruthenium and ferrocene, which may threaten safety when they are in contact with blood or body fluid due to their toxicity or pro-allergic properties.

In claims 10-13, the anode electrode and the cathode electrode contact the electrolyte solution, which is made up of blood and/or body fluid. The invention described in claims 10-13 of the present application is preferably fabricated exclusively from compounds derived from biologic organs except inert metals or graphite.

Heller teaches away from an anode electrode and a cathode electrode contacting blood or body fluid, because the biological fuel cell that Heller uses would threaten the health and safety of the recipient if the anode electrode or the cathode electrode of the biological fuel cell were in contact with blood or body fluid. The mediators taught in Heller cannot be applied to the present invention because of their potential risk to a human body.

In addition, the ultra miniature integrated cardiac pacemaker of claims 11–13 make it possible to synchronize external devices such as other cardiac pacemakers with the cardiac pacemaker of the present invention with ways to communicate information between them.

Since claims 10-13 include multiple elements not taught or suggested in Rasor et al. or Heller, alone or in combination, claims 10-13 are not obvious over these references. Reconsideration and withdrawal of the rejection of claims 10-13 are respectfully requested.

### **Conclusion**

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicants' attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

Respectfully Submitted:  
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